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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,729	08/03/2001	Steven Kiyoshi Yoshinaga	A-579B	7722

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EXAMINER	
OUSPENSKI, ILIA I	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 08/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,729	YOSHINAGA, STEVEN KIYOSHI	
	Examiner	Art Unit	
	ILIA OUSPENSKI	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *45* is/are allowed.

6)☒ Claim(s) *33-44 and 47-54* is/are rejected.

7)☒ Claim(s) *46* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/16/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 05/16/2005, is acknowledged.

Claims 1 – 32 have been cancelled.

Claims 33 – 54 have been added.

Claims 33 – 54 are pending.

2. This Office Action will be in response to applicant's arguments, filed 05/16/2005.

The rejections of record can be found in the previous Office Action, mailed 11/15/2004.

The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.

It is noted that New Grounds of Rejection are set forth herein.

3. Applicant's submission of Substitute Sequence Listing and CRF is acknowledged. The instant application now appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

4. Applicant's claim for domestic priority under 35 U.S.C. 120:

Applicant argues that claims which read on SEQ ID NOS: 16 and 17 should be entitled to the priority date of priority application USSN 09/244,448, because the Examiner has not provided any evidence that one could make antibodies which bind SEQ ID NO:17 (B7RP1 amino acids 1 – 302) but not to SEQ ID NO:12 (B7RP1 amino acids 1 – 288).

Applicant's argument has been fully considered, but is not seen as relevant, because the sequences of SEQ ID NOS: 16 and 17 have not been disclosed in priority application USSN 09/244,448, which therefore does not provide adequate support under 35 USC 112 for claims reciting these sequences.

Therefore the newly added claims which read on SEQ ID NOS: 16 or 17 (claims 35 – 44 and 46 – 54) have been accorded the priority of the filing date of USSN 09/264,527, i.e. 03/08/1999.

Should Applicant disagree with the Examiner's factual determination above, it is incumbent upon Applicant to provide a showing that specifically supports the instant claim limitations.

5. Applicant's IDS documents, filed 05/16/2005, are acknowledged, and have been considered.

Applicant's communications accompanying the IDS state that the cited references are attached, however, only references BK, BL, and CO have been located in the instant file. Applicant is invited to resubmit the remaining references to complete the record.

It is noted that in references BK and BL only the abstract is in English, and a translation has not been provided; therefore, only the Abstract has been considered.

6. Applicant's amendment has obviated the objection to claim 13 and rejections of record, set forth in the previous Office Action.

7. Claim 46 is objected to because of the following informality:

In the recitation of "as set forth or Figure 3A," it appears that "in Figure 3A" has been intended.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 33 – 44 and 47 – 54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 33 – 44 and 47 – 54 are indefinite in the recitations of "polypeptide of amino acid residues ..." and "polypeptide of Figure ...," because it is unclear whether the intended scope is that of closed language (e.g. "consisting of") or open language (e.g. "comprising"). Therefore, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

B. Claims 36 and 48 – 54 are indefinite in the recitation "but does not bind," because it is unclear whether the intended subject of the phrase is an antibody, a fragment, or both.

C. Claims 37 and 48 – 54 are indefinite, because it is unclear whether the antibody recited in claim 37 binds

a). (SEQ ID NOS:12 or 17) and SEQ ID NO:7, or

b). SEQ ID NO:12 or (SEQ ID NOS:17 and 7).

For examination purposes, the former interpretation is assumed.

D. Claims 42 and 43 are indefinite in the recitations of "agonist" and "antagonist," respectively, because the metes and bounds of these terms are unknown. The specification at page 64 defines agonists and antagonists as those molecules which increase or decrease at least one activity of a B7RP1 protein; however, it is unclear which specific activities are contemplated. Applicant is invited to amend the claims to recite specific function(s) which are increased or decreased by the claimed antibodies, from those supported by the instant specification.

E. Claim 44 is indefinite in the recitation of "immune costimulatory activity," because the metes and bounds of these terms are unknown. The term is not defined by the claim, and the specification does not appear to provide a sufficiently specific definition. Applicant is invited to amend the claim to recite specific cellular processes affected by the claimed antibodies, from those supported by the instant specification.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 36, 37, and 48 – 54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a New Matter rejection.*

Applicant's amendment asserts that no New Matter has been added and points to the specification at pages 49 – 50 and to original claim 13 for support for the newly added claims 36 and 37. However, the specification does not appear to provide an adequate written description of an antibody which binds human but not mouse B7RP1 (claim 36), or an antibody which binds both human and mouse B7RP1 (claim 37).

The instant claims now recite limitations which were not clearly disclosed in the specification and claims as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the specification or original claims, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the New Matter in the response to this Office Action.

Alternatively, Applicant is invited to clearly point out the written support for the instant limitations.

12. Claim 44 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an anti-B7RP1 antibody which inhibits B7RP1-induced T cell proliferation, does not reasonably provide enablement for an anti-B7RP1 antibody which inhibits immune costimulatory activity, as generically recited. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification does not provide a sufficient enabling description of the claimed invention.

The specification discloses that B7PR1-Fc costimulates T cells to proliferate, and that an anti-B7RP1 antibody inhibits this costimulation (Example 17 at pages 94 – 96 and Figure 15b; see especially page 96 lines 22 – 25), while the instant claim encompasses in its breadth an antibody to B7RP1 which (a) inhibits costimulatory activity of any costimulatory molecule, and (b) inhibits any aspect of costimulation.

(a). A person of skill in the art is not enabled to make and use an anti-B7RP1 antibody to inhibit costimulation induced by costimulatory molecules other than B7RP1, because it was well known in the art at the time the invention was made that costimulatory molecules have diverse structural and biochemical properties (e.g. as reviewed by Riley et al.: Blood, 2005, 105: 13 – 21; see entire document, in particular e.g. the Introduction at page 13). Therefore an antibody to one costimulatory molecule cannot be expected to inhibit costimulation induced by a distantly related costimulatory molecule.

(b). Costimulation of T cells involves a variety of changes in cell physiology, including an increase in glucose metabolism, high levels of cytokine and chemokine expression, resistance to apoptosis, and long-term expansion (reviewed by Riley et al.: Blood, 2005, 105: 13 – 21; see entire document, in particular e.g. page 14 left column). However, different costimulatory molecules do not affect all of these functions to the same degree: for example, ICOS-costimulated T cells are unable to expand long term and die of apoptosis after several cell divisions (ibid, page 15, right column, bottom paragraph). Therefore, it is highly unpredictable which subset of T cell functions, in addition to proliferation, would be affected by B7RP1, or by anti-B7RP1 antibody. Thus Applicant has not provided a sufficiently enabling disclosure regarding how to make and use an anti-B7RP1 antibody which would inhibit all aspects of costimulation, as encompassed by the instant claim language.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. Without sufficient guidance, the structural features of the claimed

antibodies are unpredictable; thus the experimentation left to those skilled in the art, is unnecessarily, and improperly, extensive and undue.

13. Conclusion: claim 45 appears to be allowable.

Claims 46 would be allowable if amended to overcome the objection set forth herein.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ILIA OUSPENSKI
Patent Examiner
Art Unit 1644

August 4, 2005

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